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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/109,858	07/02/1998	MAHENDRA S RAO	T5530.CIP	4010

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/109,858

Applicant(s)
Rao et al

Examiner
Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 6, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 15, 16, 21, 24, 26-33, and 59 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 15, 16, 21, 24, 26-33, and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 25.5 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/02 has been entered.
2. The rejection of claims 12, 15-16, 21, 23-24 & 26-33 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment of the claims and Applicants' arguments in Paper No: 25.
3. The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete is withdrawn due to the amendment of the claims.
4. The rejection of claims 21 & 23 under 35 U.S.C. 102(b) as being anticipated by Blass-Kampmann et al. (1994), is withdrawn due to the amendment or cancellation of the claims.

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5. The rejection of claims 12, 15-16, 24, 28-33 under 35 U.S.C. 103(a) as being unpatentable over Blass-Kampmann et al. (1994), in view of Boss et al, Weiss et al., Johe et al., Rao et al, and/or Lee et al. is withdrawn due to the amendment of the claims.

6. Applicant's arguments filed 5/03/02 and 8/06/02 have been fully considered but they are not deemed to be persuasive.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claim 59 is re-instated as being rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons made of record in Paper Nos: 5, 10 & 17 for obtaining and using human embryonic stem (ES) cells.

It is noted that claim 59 again recites "*human* embryonic stem cells" that was previously removed in amendment C (paper #18), and that neither amendments D, E & F provide a proper "marked-up copy" for re-adding this recitation, as required under the AIPA Rules. In any case, note that the court in *In re Hogan and Banks*, 194 USPQ 527 (1977) makes clear that enablement

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must be established in the specification *at the time of filing* and is to be *commensurate in scope* with the stated claims, in which the current application claims a priority date of 7/04/97.

9. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

The omitted steps are: no initial differentiation step is recited for obtaining CNS neuron-restricted precursor cells from ES cells. Second, page 55 of the specification discloses that ES cells do not express A2B5, so it is confusing what step (b) is envisioned to accomplish, as currently recited. Lastly, if the claims are amended to recite a differentiation step, it is ambiguous how differentiation to only “CNS neuron-restricted precursor cells” is achieved, versus continued differentiation to neurons and glial, or more importantly to any other cell type which is not a CNS cell.

10. Claims 12, 15-16, 21, 24, 26-33 & 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unknown what metes and bounds exactly constitutes or differentiates “adherent growth supporting medium” from “retinoic acid containing medium” from “astrocyte-promoting medium” from “feeder-cell-independent culture” from “proliferating conditions” from

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“differentiating conditions”; especially when both “adherent growth supporting medium” and “astrocyte-promoting medium” contain “FGF” (e.g., as it relates to claims 12 & 28-33), etc., which further confuses what exactly is envisioned as the required medium to practice the invention. Likewise, the metes and bounds of “plated at a temperature and in an atmosphere conducive to growth” (i.e., as it relates to claims 21 & 59) are unknown and do not appear to be defined in the specification (e.g., on page 55).

Note that it appears that only NEP medium is defined in the specification (e.g., pg. 22). Note further that attempts to incorporate subject matter into this application by reference to a journal article is improper because only U.S. patents and U.S. applications are proper incorporations by reference (e.g., pg. 31), if the incorporated material is required to practice the claimed invention.

11. Claims 15 & 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No antecedent basis for “said procedure” or “said mammalian” now exists in base claim 12 (i.e., as it relates to claims 15 & 16, respectively).

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12. Claims 26-27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Blass-Kampmann et al. (1994), for the reasons made of record in Paper Nos: 5, 10 & 22.

13. Claim 26-28, 29 & 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Boss et al. (U.S. Patent 5, 5,411,883).

In contrast to Applicants' assertions on page 13 of the response, Example 12 of the specification does not define what constitutes a "pure population". In that Example 12 merely discloses isolation protocols/ immunopanning similar to Boss et al. (e.g., col. 12), the same level of purity is reasonably obtained by Boss et al.; absent evidence to the contrary.

In summary, Boss et al. teach a method of using differentiating conditions to obtain postmitotic neurons (e.g., col. 13-14), which includes addition of the neuronal maturation factor, retinoic acid (i.e., as it relates to claims 29 & 32-33).

Boss et al. further teach methods of obtaining pure populations of neuron-restricted precursor cells using FACS or magnetic bead sorting (e.g., column 12, lines 54-61), in which column 19 (lines 29-30) states "eight replicate aggregate cultures of human neuron progenitor cells prepared as described above..." (i.e., as it relates to claims 26-27 & 28). However, it is noted that Boss does not disclose what specific antibodies are to be used, etc., which may obviate the method claims rejected under 102(e), if claim 28 is amended to recite antibodies to be used, etc., and/or is amended to "pure population of neuron-restricted cells obtained by the method of claim 12."

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14. Claims 26-27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Blass-Kampmann et al. (1994), for the reasons made of record in Paper Nos: 5, 10 & 22.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
January 15, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600